DRAFT PA Criteria

INITIAL APPROVAL: JULY 11, 2018
REVISED DATES: OCTOBER 9, 2019;
JULY 10, 2019; OCTOBER 10, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Antidepressant Medications – Safe Use for All Ages

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.
~~**PROVIDER GROUP** Pharmacy~~
~~Professional (Spravato™ Only)~~

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available of the medications below:
~~**MANUAL GUIDELINES** The following drugs (all strengths and dosage forms) require prior authorization as outlined in the criteria below:~~

Amitriptyline (Elavil®)
Amoxapine
Bupropion (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)
Citalopram (Celexa®)
Clomipramine (Anafranil®)
Desipramine (Norpramin®)
Desvenlafaxine (Khedezla®, Pristiq®)
Doxepin (~~Silenor~~Sinequan®)
Duloxetine (Cymbalta®, Drizalma Sprinkle™)
Escitalopram (Lexapro®)
Esketamine (Spravato®)
Fluoxetine (Prozac®, Prozac Weekly®)
Fluvoxamine (Luvox®, Luvox CR®)
Imipramine (Tofranil®, Tofranil® PM)
Isocarboxazid (Marplan®)
Levomilnacipran (Fetzima®)
Maprotiline
Milnacipran (Savella®)
Nefazodone
Nortriptyline (Pamelor®)
Olanzapine/Fluoxetine (Symbyax®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)
Phenelzine (Nardil®)
Protriptyline (Vivactil®)
Selegiline (Emsam®)
Sertraline (Zoloft®)
Tranylcypromine (Parnate®)
Trimipramine (Surmontil®)
Venlafaxine (Effexor®, Effexor XR®)
Vilazodone (Viibryd®)
Vortioxetine (Trintellix®)

CRITERIA FOR PRIOR AUTHORIZATION FOR ANTIDEPRESSANTS MEDICATIONS:

- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.

- MULTIPLE CONCURRENT USE:
  - Each of the following criteria for multiple concurrent use will require prior authorization:
    - For patients **< 13 years of age**, two or more different antidepressants used concurrently for greater than 60 days
    - For patients **≥ 13 years of age**, three or more different antidepressants used concurrently for greater than 60 days
    - Two or more different selective serotonin reuptake inhibitors (SSRIs) used concurrently for greater than 60 days (defined in table 1)
    - Two or more different serotonin norepinephrine reuptake inhibitors (SNRIs) used concurrently for greater than 60 days (defined in table 2)

- Two or more different tricyclic antidepressants (TCAs) used concurrently for greater than 60 days (defined in table 3)

- Prior authorization will require written peer-to-peer consult with health plan psychiatrist, medical director, or pharmacy director for approval, followed by a verbal peer-to-peer if unable to approve written request.

LENGTH OF APPROVAL: 12 months

RENEWAL CRITERIA: Patient is stable and has been seen in the past year.

CRITERIA FOR PRIOR AUTHORIZATION FOR ESKETAMINE (SPRAVATO™) NASAL SPRAY:

- Age ≥ 18 years of age.[4]
- Patient must have a diagnosis of treatment-resistant depression, including ALL of the following:
  - DSM-5 criteria for major depressive disorder.
  - Inadequate response (in the current episode) to at least 2 different antidepressants (listed in Tables 1-4) despite therapeutic dose and 6 weeks[1] duration of each medication.
- Patient must be started on a new oral antidepressant in conjunction with esketamine.
- Patient must have an adequate trial (at least 4 weeks) of at least ONE of the following augmentation therapies, or a contraindication to all therapies listed in Table 5:[1]
  - Addition of a second-generation antipsychotic listed in Table 5 to the current regimen.
  - Addition or change in medication therapy to a fixed-dose combination product of olanzapine/fluoxetine.
- Prescriber must provide baseline Montgomery-Asberg Depression Rating Scale (MADRS) or- Hamilton Depression scale (HAM-D) before initial treatment with intranasal esketamine.
  - Patient must have severe depression as defined by MADRS or HAM-D..
  - ~~Patient must be assessed with the MADRS at least quarterly.~~
- Patient, provider, and provider's staff must be registered, educated, and be in good standing with the associated REMS program.
- Dose does not exceed 168mg (6 nasal spray devices) per week for induction (initial 4 weeks).[4]
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance (beyond initial 4 weeks).[4]
- Patient must be screened for active/risk for substance use disorder.
- Prescriber has addressed the appropriateness of psychotherapy with the patient.

LENGTH OF INITIAL APPROVAL: 6 months

RENEWAL CRITERIA:

- ~~Documented evidence of significant treatment benefit/improvement beyond previously tried regimens, i.e. patient is in remission or partial remission~~Prescriber must provide the following response measure(s).
  - Stable response was maintained, defined as MADRS or HAM-D decrease ≥50% from baseline, for the majority of the assessments since the most recent approval.
- Patient has < 2 relapses since the most recent approval. A relapse is defined as hospitalization or overnight observation for worsening depression.
- Patient must be screened for active/risk for substance use disorder.
  ~~Negative drug screen.~~
- Dose does not exceed 84mg (3 nasal spray devices) per week for maintenance.[4]

LENGTH OF APPROVAL FOR RENEWAL: 12 months

TABLE 1. SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)

SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)
Citalopram (Celexa®)
Escitalopram (Lexapro®)
Fluoxetine (Prozac®, Prozac Weekly®)
Fluvoxamine (Luvox®, Luvox CR®)
Paroxetine (Paxil®, Paxil CR®, Pexeva®)
Sertraline (Zoloft®)
Vilazodone (Viibryd®)*
Vortioxetine (Trintellix®)**

*Vilazodone also has partial agonistic 5-HT_{1A} activity
**Vortioxetine also has agonistic 5-HT_{1A} and antagonistic 5-HT_3 activity

TABLE 2. SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIS)

SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIS)
Desvenlafaxine (Khedezla®, Pristiq®)
Duloxetine (Cymbalta®, Drizalma Sprinkle™)
Levomilnacipran (Fetzima®)
Milnacipran (Savella®)
Venlafaxine (Effexor®, Effexor XR®)

TABLE 3. TRICYCLIC ANTIDEPRESSANTS (TCAS)

TRICYCLIC ANTIDEPRESSANTS (TCAS)
Amitriptyline (Elavil®)
Amoxapine
Clomipramine (Anafranil®)
Desipramine (Norpramin®)
Doxepin (Sinequan®)
Imipramine (Tofranil®)
Imipramine Pamoate (Tofranil® PM)
Nortriptyline (Pamelor®)
Protriptyline (Vivactil®)
Trimipramine (Surmontil®)
TETRACYCLIC ANTIDEPRESSANTS
Maprotiline

TABLE 4. OTHER ANTIDEPRESSANTS

DOPAMINE NOREPINEPHRINE REUPTAKE INHIBITORS
Bupropion (Forfivo® XL, Wellbutrin®, Wellbutrin® SR, Wellbutrin® XL)
SEROTONIN MODULATORS
Nefazodone (Serzone)
Monoamine Oxidase Inhibitors (MAOIs)
Phenelzine (Nardil®)
Tranylcypromine (Parnate®)
Isocarboxazid (Marplan)

Selegiline transdermal system (Emsam®)

TABLE 5. AUGMENTATION THERAPIES[1,5-8]

SECOND-GENERATION ANTI-PSYCHOTICS (SGAS)
Aripiprazole (Abilify®)
Brexpiprazole (Rexulti®)
Olanzapine/fluoxetine (Symbyax®) (fixed combination product)
Quetiapine Extended Release (Seroquel XR®)

Notes:

- Mirtazapine, and trazodone are FDA-indicated for depression, but are not listed because they are primarily used for other indications.

References:

1. Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition. American Psychiatric Association, October 2010. Available at https://psychiatryonline.org/guidelines. Accessed 7/24/19.
2. Psychotropic Medication Utilization Parameters for Children and Youth In Foster Care (5th Version). Texas Department of Family and Protective Services and The University of Texas at Austin College of Pharmacy, March 2016 (updated July 2016). Available at http://texaschildrenscommission.gov/reports-and-resources/. Accessed 8/6/19.
3. Maust, D, Cristancho M, et al. Chapter 13 – Psychiatric rating scales. Neurobiology of Psychiatric Disorders. Handbook of Clinical Neurology, 2012. Available at https://www.sciencedirect.com/topics/medicine-and-dentistry/montgomery-asberg-depression-rating-scale. Accessed 7/23/19.
4. Spravato (esketamine) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2019.
5. Abilify (aripiprazole) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2017.
6. Rexulti (brexipiprazole) [package insert]. Otsuka America Pharmaceutical, Inc.; February 2018.
7. Symbyax (olanzapine/fluoxetine) [package insert]. Indianapolis, IN: Lilly USA, LLC; March 2018.
8. Seroquel XR (quetiapine) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

DATE

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE